K070676

Special 510k
Korebalance Kinesthetic Ability Trainer
SportKAT, LLC

## 510k Summary

APR 18 2007

**510k Owner:**
SPORTKAT, LLC
1497 Poinsettia Avenue, Suite 157
Vista, CA 92083
FDA Registration #: 2031091

**Contact:**
Mr. Damon Lawson
Cell (812) 212-2020
Phone: (858) 866-3393
FAX: (858) 866-3933

**Summary Date:** March 6, 2007

**Device Trade Name:** Korebalance™ Kinesthetic Ability Trainer
**Common or Usual Name:** Apparatus, Vestibular Analysis (Computerized Postural Pressure Platform)
**Classification:** Unclassified
**Product Code:** LXV

**Predicate Device:** This Special 510k is for changes to the previously cleared K.A.T. 1000 device (K911795)

**Device Description:** The updated Korebalance™ Kinesthetic Ability Trainer device has the same intended use and incorporates the same balance board (platform) and bladder design technology as the originally cleared device. The modifications are primarily software based and allow:

1. Creation of a patient specific electronic record of patient information via a touchscreen GUI.
2. Quantitative measurement of patient balance performance while the patient executes a preprogrammed set of maneuvers or protocols with the board. The GUI provides instructions and visual feedback to the patient with regard to the maneuvers to be made and the success in executing the maneuver. The patient results are scored and saved (the information is not a clinical measurement but provides a reproducible quantitative measurement that the therapist can use to plan and monitor therapy) along with the bladder pressure measurement for use by the therapist, in conjunction with the therapist's observations, to assess patient progress over the course of multiple therapy sessions. Specific protocols are provided for vestibular training, orthopedic therapy, and falls prevention. These protocols are similar to those used with the previously cleared device.

3. Patients to play "games" displayed on the GUI that involve performing various maneuvers on the balance platform. Performance is scored. The games provide an additional means for the therapist to provide rehabilitation that is fun and challenging for patients.

**Indications for Use:** The Korebalance™ device is intended for use in balance therapy, only by health care professionals with experience in balance therapy. Patient suitability must be judged by the health professional on a case by case basis.

**Substantial Equivalence:** The modified device has the following similarities to the original previously cleared device:

- It has the same intended use
- It incorporates the same balance board and bladder design technology
- The degree of difficulty is adjustable
- The device provides a quantitative measure of performance

Modifications include the addition of a GUI, and a computer with software that allows the entry of patient specific information, the selection of static and dynamic preprogrammed tests, test selection and the measurement and the optional storage of patient performance information. The addition of modern 3-D games provides a means for patients to increase their balance board skills under the therapist's guidance in an enjoyable manner. The changes do not materially alter the intended use or fundamental technology of the device, but serve to facilitate the provision of therapy, data collection and management.

**Testing:** The modifications to the existing device were made in accordance with the design control provisions of the quality system regulation and applicable guidance documents to show that the modified device is as safe, as effective, and performs as well as or better than the original device .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2007

SPORTKAT, LLC
c/o Damon R. Lawson
1497 Poinsettia Avenue, Suite 157
Vista, CA 92083

Re: K070676
Trade/Device Name: Korebalance Kinesthetic Ability Trainer
Regulation Name: Vestibular Analysis Apparatus
Regulatory Class: Unclassified
Product Code: LXV
Dated: March 5, 2007
Received: March 19, 2007

Dear Mr. Lawson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070676

Special 510k
Korebalance Kinesthetic Ability Trainer
SportKAT, LLC

## Indications for Use

510(k) Number (if known): K070676

Device Name: Korebalance™ (Kinesthetic Ability Trainer)

Indications for Use: The Korebalance™ device is intended for use in balance therapy, only by health care professionals with experience in balance therapy. Patient suitability must be judged by the health professional on a case by case basis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801. 109)

OR

Over-The-Counter Use_____

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K070676

**Prescription Use** X
**(Per 21 CFR 801.109)**